



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substance and Disease Registry

[60Day-18-18AJK Docket No. ATSDR-2018-0002]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled "Per- or Polyfluoroalkyl Substances (PFAS) Exposure Assessments." ATSDR and the CDC National Center for Environmental Health (NCEH) will conduct a minimum of eight exposure assessments (EAs) at current or former military installations with known PFAS contamination in drinking water, groundwater, or another water source.

DATES: ATSDR must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. ATSDR-2018-0002 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. ATSDR will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information

they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of

information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Per- or Polyfluoroalkyl Substances (PFAS) Exposure Assessments - New - Agency for Toxic Substances and Disease Registry (ATSDR) and the National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Per- and polyfluoroalkyl substances (PFAS) are a large group of man-made chemicals that have been used in industry and consumer products worldwide since the 1950s. Although some PFAS are no longer produced in the United States, they many remain in the environment and may impact people's health. Thus, PFAS are contaminants that have gained national prominence over the last decade.

Under Section 8006 of the Consolidated Appropriations Act, 2018, the Agency for Toxic Substances and Disease Registry and CDC National Center for Environmental Health {ATSDR/NCEH} are requesting a three-year Paperwork Reduction Act clearance for a new information collection request (ICR). ATSDR/NCEH will

conduct EAs at current or former domestic military installations known to have PFAS in drinking water, groundwater, or any other sources of water. The annualized number of EAs assumes the following. ATSDR/NCEH will conduct a minimum of eight EAs, but ATSDR/NCEH may complete an additional seven for a total of 15 EAs. Therefore, ATSDR/NCEH anticipates conducting five PFAS EAs each year for three years.

All eligible respondents will be consented before being included in each EA. The consent forms will include adult consent, and parental permission and child assent forms, as appropriate. Each consented respondent will provide a serum and a urine sample. In addition, heads of households from ten percent of households using tap water for their drinking water will consent to provide tap water and indoor dust samples. The consent forms will include permission to store some biospecimens and environmental samples for future analysis and will include permission to recontact respondents for potential investigations or studies in the future. ATSDR will also collect contact information to provide respondents with their individual sampling results.

Household Eligibility Screener: ATSDR/NCEH will conduct the PFAS EAs in communities with populations living on or near current or former military installations. ATSDR/NCEH will recruit a desired sample size of 379 respondents per EA (1,895

total per year) using statistical household sampling methods. Eligibility criteria for individuals include specific age intervals (i.e., children older than three years given the lack of NHANES comparison data for younger children), lack of bleeding disorders that would prevent a blood draw, and time of residency (i.e., at least one year in the home).

Applying an average U.S. household size of 2.5 members, per EA, ATSDR/NCEH will enroll respondents from 152 eligible households ($379/2.5$). To identify the 152 eligible households, we further assume a 65 percent household eligibility rate. This will require administering a 5-minute eligibility screener to 234 heads-of-households per EA ($152 \times 100/65$), or to 1,170 heads-of-households per year (234×5). The annual time burden requested for eligibility screening is 98 hours.

Exposure Assessment Questionnaire for Biological and Environmental Testing for Adults, Parents, or Children:
ATSDR/NCEH will administer an exposure questionnaire to all consented respondents that includes questions associated with potential exposure to PFAS both inside and outside the home (e.g., work or school). In addition, the adult questionnaire also includes several questions associated with water use and flooring type while the child questionnaire includes questions regarding playing in soil; these questions are intended to evaluate potential exposure and to support the environmental

testing. The time associated with administering the questionnaire and completing the biological sampling is approximately 30 minutes for 1,440 adults (720 hours). The time associated is 15 minutes for 264 parents responding for their children, 3-11 years old (66 hours), and for 191 children, 12-17 years old, who respond for themselves (48 hours). ATSDR/NCEH will use the questionnaire and laboratory results to identify likely exposure scenarios.

Household Recruitment Script for Environmental Sampling: The households providing environmental samples will be randomly selected from households that report using tap water for drinking water. ATSDR/NCEH will recruit 10 percent subset of these eligible households to collect tap water and indoor dust samples. Assuming a 65 percent response rate, ATSDR/NCEH will administer a 5-minute recruitment script to 23 heads-of-households who are eligible to take part in each EA ($152/10 \times 100/65$). The time required to administer the recruitment script is 5 minutes. This will result in annual recruitment from 117 heads-of-households and 10 hours for five EAs.

Environmental Sample Collection Form: Again, assuming a 65 percent response rate, to meet our sample size goal of 10 percent of eligible households, ATSDR/NCEH will consent and collect samples from approximately 15 households per EA or

households annually ($152 \times 10 / 100 \times 5$). The average time burden is estimated as 15 minutes per response, or 19 hours annually.

ATSDR estimates the total annualized time burden is 961 hours. Participation is voluntary, and there are no costs to respondents other than their time.

Public health professionals, environmental risk managers, and other decision makers can use EA results to make informed decisions about the sources and impact of PFAS contamination in environmental media within their own community and jurisdiction. The data will support their recommendations for public health actions to reduce or eliminate harmful levels of PFAS in the local environment. These EAs are not intended to yield information about PFAS exposure that will be generalized beyond the defined boundaries of each investigation; however, ATSDR/NCEH will use these EA findings to inform a future national PFAS health study.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Potential EA Heads-of-Households	Household Eligibility Screener	1,170	1	5/60	98
EA Adults	<u>Exposure Questionnaire for Biological and Environmental Testing (Adults)</u>	1,440	1	30/60	720
EA Parents	EA Questionnaire for Biological Testing (Child)	264	1	15/60	66
EA Children	EA Questionnaire for Biological Testing (Child)	191	1	15/60	48
EA Heads-of-Households	<u>Household Recruitment Script for Environmental Sampling</u>	117	1	5/60	10
	<u>Environmental Sample Collection Form</u>	76	1	15/60	19

Total					961
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Jeffrey M. Zirger,
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Information Collection Review Office,
Office of Scientific Integrity,
Office of the Associate Director for Science,
Office of the Director,
Centers for Disease Control and Prevention.
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